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DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

June 23, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Douglas A. Wankier
Branch Manager
Interwest Home Medical, Inc.
235 East 6100 South
Salt Lake City, UT 84107

PURGED

Ref. # - DEN-97-22

Dear Mr. Wankier:

During an inspection of your firm, Interwest Home Medical, Inc., located at 235 East 6100 South, Salt Lake City, Utah, on March 14 through 17, 1997, Investigator James E. Moore II determined that your firm repacks liquid and compressed medical oxygen. Medical gases are drug products as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your produ .ts are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with current Good Manufacturing Practice regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. Failure to calibrate oxygen analyzers in accordance with manufacturer's directions and your firm's written procedures to assure proper performance, as required by 21 CFR 211.160(b)(4). For example:

   a. your firm does not have a Certificate of Analysis for the reference cylinder of oxygen, used for calibrating the [redacted] oxygen analyzer, certifying that it meets the minimum requirements set forth in the [redacted] Owner's Manual;

b. the Certificate of Analysis for the reference cylinder of nitrogen is not valid as it does not contain the date of analysis, the method used for analysis or the signature of the person performing the analysis as required by your firm's written procedures; and,

c. the reference cylinders of oxygen and nitrogen are not labeled as calibration gases as required by your firm's written procedures.

2. Failure to perform adequate prefill inspections on each high pressure cylinder prior to filling, as required by 21 CFR 211.84(d)(3).

3. Failure to retest cryogenic home units for identification after service or repair, prior to redistribution, as require by 21 CFR 211.87.

4. Failure to routinely calibrate equipment in accordance with written procedures as required by 21 CFR 211.68(a). Your firm's written procedures require calibration of all gauges and thermometers on an annual basis.

   a. the [redacted] thermometer model [redacted] used in cylinder transfilling has not been calibrated since May 28, 1993; and,

   b. neither the vacuum gauge nor the pressure gauge used for cylinder transfilling have been calibrated since May 19, 1992.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters for drug products so that they may take this information into account when considering the award of contracts.

These deviations may be indicative of corporate wide non-compliance. We recommend that internal audits be conducted at all your medical gas facilities and appropriate action be taken to assure that similar violations are not occurring at other locations.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

Please advise this office, in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations.

Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved.

Your response should be directed to Mr. David K. Glasgow, Acting Compliance Officer, at the above address.

Sincerely,

Gary C. Dean
District Director

Enclosures:
As Stated

cc: Mr. James Robinson
President
Interwest Home Medical, Inc.
235 East 6100 South
Salt Lake City, UT 84107

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